MAR - 7 2012

K113284

FUJIFILM MEDICAL SYSTEMS U.S.A., INC.

FUJIFILM

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510(k) Summary

Date Prepared: **November 4, 2011**

Submitter's Information

FUJIFILM Medical Systems U.S.A., Inc.
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Contact: Kimerly A. Sharp

Device Name and Classification:

Product Name:	Biopsy Positioner
Model Number:	FDR-1000BPY
Classification Name:	Mammographic X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR 892.1710
Device Class:	Class II
Product Code:	IZH

Substantial Equivalence/Predicate Device:

Hologic Affirm Breast Biopsy Guidance System (K103512)

The FUJIFIM Biopsy Positioner (FDR-1000BPY) is substantially equivalent to the Hologic Affirm Breast Biopsy Guidance System (used with Selenia Dimensions 2D FFDM) which is a stereotactic lesion localization system that has the application of localizing, and then giving a physician the capability of performing fine needle aspiration or core biopsy of lesions determined to be suspicious through prior mammographic examination

Description of the Device:

The FUJIFILM Biopsy Positioner is an optional accessory for the Aspire HD (FDR MS-1000) full field digital mammography system and future Fujifilm digital mammography exposure stands. It is designed for positioning the needle when performing stereotactic biopsies, fine needle aspirations, core needle, and vacuum assisted biopsies in an upright position. The Biopsy Positioner uses a stereo pair of images, taken with the tube arm angled to +15° and -15° from vertical (orthogonal to the plane of the image receptor). The position of the three coordinates (X, Y, and Z) is computed using the position of the object on each of the two images, as indicated by the operator, and the known geometry of the system.

The Biopsy Positioner is composed of the following elements:

- The Positioner that supports and positions the needle
- The Operation panel which displays the distance between the compression plate and target pathology, the distance between the target pathology and the needle, and also electrically drives the positioner in the X, Y and Z directions.
- The Positioner Control Unit which supplies power to the positioner

The FUJIFILM Biopsy Positioner slides onto the Aspire HD image receptor. The cable from the positioner control cabinet has two connectors which are plugged into the lower part on the front of the exposure stand. The operation panel is then attached to one of the armrests. Stereotactic images are acquired at +/- 15°. The biopsy software processes and displays the images on the Acquisition Workstation (AWS) for targeting procedure. Targeting procedure involves checking the same object on each image which results in setting the target mark. The software calculates the three-dimensional coordinates of the target pathology with position accuracy of -/+1.0mm or less. When targeting is completed, the three-dimensional coordinates of the target pathology are calculated based on the target mark at one position of each stereo image. The positioner can be moved by operating the dials for X, Y and Z axes or via the electric drive buttons on the operation panel (Z axis movements are manually applied when needle is connected).

Safety Features include:

- An audible alarm will sound from the operation panel under the following conditions:
  (Unless appropriate action is taken, the alarm will continue to sound)
  - The Positioner is not locked to the exposure unit.
  - Needle end is positioned less than 4.0mm from exposure table surface prevents collision.
  - The needle holder is attached and the positioner is within 20mm from the top end in the Z direction (prevents the needle and the tube from interfering with each other).

- The Stereo Biopsy Software displays information on the selected needle, the impossibility of a study, precautions for executing a study, etc.

- Target Position is shown via diagram on the display screen

Intended Use:

The FUJIFILM Biopsy Positioner (FDR-1000BPY) is an optional accessory for the Aspire HD (FDR MS-1000) digital mammography system. It is designed to allow for accurate determination of three dimensional lesion locations in the breast using information extracted from stereotactic pairs of two-dimensional images. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices).

Safety Information:

The Biopsy Positioner introduces no new safety or efficacy issues other than those already identified with the predicate devices. The results of the Hazard Analysis combined with the appropriate preventive measures taken indicate that the device is of moderate concern as per the May 11, 2005 issue of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." And consistent with that indicated in the "Class II Special Controls Guidance Document: Full-Field Digital Mammography System" document issued on: November 5, 2010.

Summary of Testing:

This equipment conforms to the following:

- IEC 60601-1-2:2001+A1:2004
- IEC 60601-1:1988 + A1:1991 +A2:1995
- IEC 60601-1-1:2000
- IEC 60601-2-45: 2001
- IEC 62304: 2006

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- DICOM (Version 3)

Conclusion:

This 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health. We conclude the subject device to be as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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Ms. Kimerly A. Sharp
RA/QA Specialist
FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
STAMFORD CT 06902

Re: K113284
Trade/Device Name: Biopsy Positioner (FDR-1000BPY)
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: IZH
Dated: January 20, 2012
Received: January 23, 2012

Dear Ms. Sharp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113284

Device Name: Biopsy Positioner (FDR-1000BPY)

Indications for Use:

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Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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